Appl. No. 10/791,166 Amdt. dated May 17, 2005 Reply to Office Action of February 23, 2005

REMARKS/ARGUMENTS

Claims 1-17 are pending in the application. Claims 1, 6-8, 10 and 15-17 have been amended. Claims 5 and 14 have been canceled. Entry of the amendment, reconsideration of the rejection, and allowance of claims 1-4, 6-13 and 15-17 are respectfully requested.

The Amendment

In order to expedite prosecution of the application and advance the case toward allowance, the claims have been amended. No new matter was added by the amendment.

Claims 1 and 10 have been amended as suggested by the Examiner, wherein the claims have been further clarified by specifying that the antagonist is an antibody or binding fragment thereof which binds to the MCP-1 receptor polypeptide. Support for this amendment can be found, for example, in original claims 5 and 14 and in the specification on pages 24-25, paragraphs 0084-0090.

Claims 6-8 and 15-17 have been amended to correct for proper dependency.

Information Disclosure Statement

The Office Action indicates that the information disclosure statement (IDS) filed in June 2004 only contains sheets 3 through 5 and the Applicants are invited to supply copies of sheets 1 and 2. Applicants state for the record that the labeling of the IDS sheets as 3-5 was an unintentional error since the IDS contained only 3 sheets in total. In order to correct this error, Applicants herewith submit a corrected IDS with the proper labeling of the sheets as 1 through 3 and request that the Examiner enter the corrected IDS.

Drawings

The drawings are objected to because of informalities. Specifically, Figures 1, 2, 3, 4 and 7 contain multiple subcomponents that are not described in the specification and a drawing correction or corrected drawings are required in reply to the Office Action.

In response, the specification has been amended to refer to the multiple subcomponents within the description of the Figures. No new matter was added by this

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amendment. It is respectfully requested that the Examiner withdraw the objection in light of this amendment.

Rejections Under 35 U.S.C. §112

Claims 1-9 and 10-17 are rejected under 35 U.S.C. §112, first paragraph, as being a allegedly not enabled. However, the Examiner states that the specification is enabling for a method of inhibiting a condition characterized by monocytic infiltrates or inhibiting MCP-1 receptor polypeptide, wherein said method comprises administering to a patient a therapeutically effective amount of MCB-1 antagonist in a suitable pharmaceutical carrier, wherein said MCP-1 receptor antagonist binds to an MCP-1 receptor polypeptide and wherein said antagonist is an antibody or binding fragment thereof which binds to a MCP-1 receptor. The Examiner further states that the specification provides sufficient guidance for us of an antibody or antibody binding fragment thereof which binds the MCP-1 receptor.

In order to advance the case toward allowance, the claims have been amended according to the Examiner's suggestion. As such, the claims have been amended to specify that the antagonist is an antibody or binding fragment thereof which binds to a MCP-1 receptor. In light of this amendment, the rejection is moot and it is respectfully requested that the Examiner withdraw the rejection and place the claims into condition for allowance.

Claims 1-4 and 9-13 are rejected under 35 U.S.C. §112, first paragraph, as allegedly lacking written description. The Office Action states that the instant Applicant does not provide the structure and/or identity of any MCP-1 receptor antagonists except for antibodies which bind SEQ ID NO: 2 or SEQ ID NO: 4. The Examiner concludes that the instant situation is most analogous to the University of Rochester case (*University of Rochester v. G.D. Searle & Co.*, 68 USPQ2d 1424 (DC WNY 2003) and *University of Rochester v. G.D. Searle & Co. et al.* CAFC [(03-1304) 13 February 2004]), wherein the written description was not satisfied because the patent described a compound's desired function but did not identify the compound since the invention consisted of performing assays to screen compounds in order to discover those with desired effect.

The rejection is respectfully traversed to the extent that the rejection applies to the claims as amended.

As shown above, the claims have been amended to specify that the antagonist is an antibody or binding fragment thereof which binds to the MCP-1 receptor polypeptide. Claims 2 and 11 further define the invention by indicating that the MCP-1 receptor polypeptide comprises the amino acid sequence of SEQ ID NO: 2 or SEQ ID NO: 4 (see also page 6 of the specification and Figures 1 and 2). Thus, the invention has been fully described such that the skilled artisan would recognize what is claimed. As the Examiner correctly indicated on page 15 of the Office Action, the patent at issue in the University of Rochester case "did not name even one compound that assays would identify as suitable for practice of the invention, or provide information such that one skilled in the art could identify a suitable compound". This scenario differs from the instant invention since the Applicants have provided ample teachings and description of how an antagonist such as an antibody that binds to the MCP-1 receptor polypeptide can be used and identified (see pages 24-25, paragraphs 0084-0090).

In light of the amendment and arguments presented above, Applicants respectfully request that the rejection of claims 1-4 and 9-13 under 35 U.S.C. §112, first paragraph, be withdrawn.

CONCLUSION

In view of the foregoing, Applicants believe all claims now pending in this Application are in condition for allowance. The issuance of a formal Notice of Allowance at an early date is respectfully requested.

If the Examiner believes a telephone conference would expedite prosecution of this application, please telephone the undersigned at 415-576-0200.

Respectfully submitted,

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